

MAY 21 2014

510(k) Summary**DATE** May 21, 2014**General Information**

Trade Names: M913 Medikro® Nano, M914 Medikro® Primo and M915 Medikro® Pro

Common Name: Spirometer, Diagnostic Spirometer

Classification Name: Spirometer, Diagnostic Spirometer (21 CFR 868.1840, Product Code BZG)

Classification: Class II

Manufacturer: Medikro Oy
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Predicate Devices: Caird Technology Spirometer, K971336

Welch Allyn CardioPerfect Workstation, Software Version 1.5.0, K052158

Device Description

Medikro® spirometer runs on a personal computer with Microsoft Windows operating systems.

Medikro® spirometer unit is connected to PC via USB port (USB model). SpiroSafe disposable flow transducer is connected to the spirometer unit via pressure tube. Nose clip is used to prevent air flow from nose during measurements. Optional calibration syringe is used for recommended daily volume calibrations.

Medikro® spirometers are used to measure lung air volume and airflow rate. Medikro® Spirometry Software is used to perform the measurement and calculate the measurement volume based on chosen reference value. The reference value is based on patient's gender, race and age. User can analyze the results in different presentations and create a final report

based on the results and patient information. For details about tested reference values see: Tab Software Verification and Validation.

The spirometers take all the power that it needs from the USB port, so no other external or internal power supply is needed.

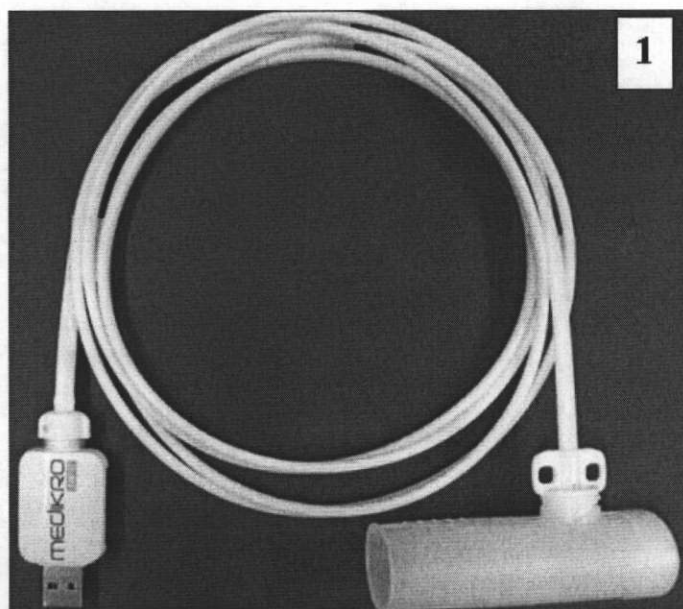


Figure 1: M913, Medikro® Nano spirometer with Pressure Tube and Disposable Flow Transducer

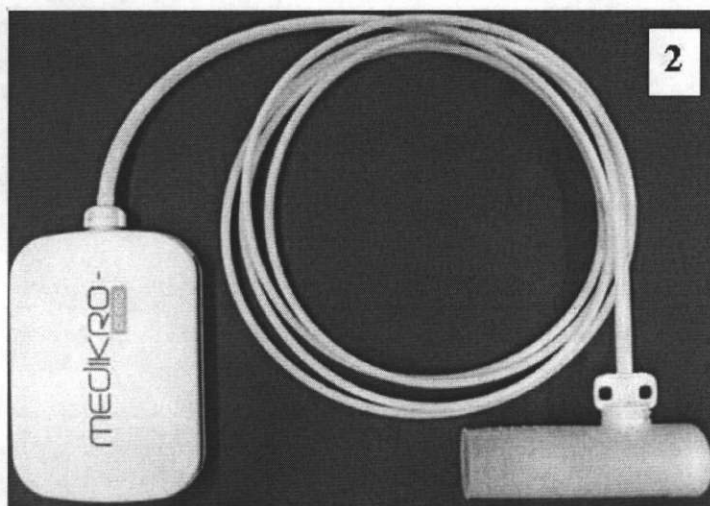


Figure 2: M914, Medikro® Primo spirometer with Pressure Tube and Disposable Flow Transducer

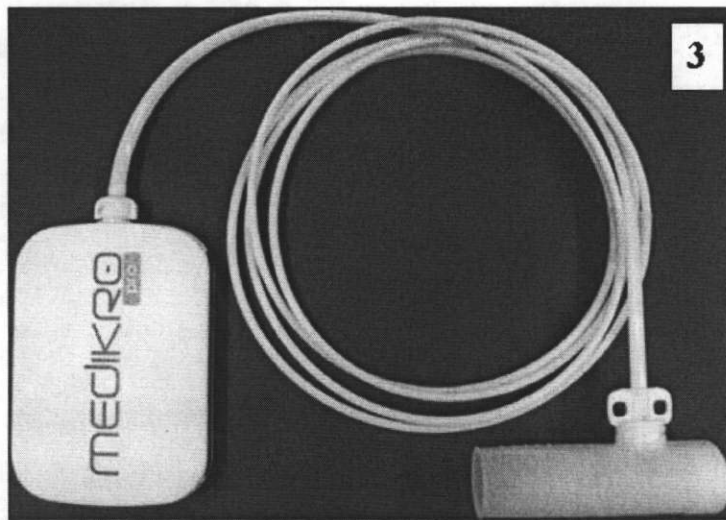


Figure 3: M915, Medikro® Pro spirometer with Pressure Tube and Disposable Flow Transducer

Indications For Use:

Medikro® Spirometer is a device that measures lung air volume and airflow rate for pulmonary disease diagnosis and screening. These measurements provide information about a patient's pulmonary function which may be compared with normal values or the patient's previous values.

The device is designed to test pulmonary function and obtain spirometric indices for

- adult and pediatric patients 12 years and older,
- hospital and clinic use only.

Key Technological Characteristics

| Feature | Predicate Device 510(K) Number K971336 | Predicate Device 510(K) Number K052158 | New devices M913 Medikro® Nano, M914 Medikro® Primo M915 Medikro® Pro |
|---------------------------------------|--|--|--|
| Device classification | Spirometer, diagnostics | Spirometer, diagnostics | Spirometer, diagnostics |
| Target population | Adult and pediatric patients | Adult and pediatric patients | Adult and pediatric patients |
| Use environment | Hospital/Clinical | Hospital/Clinical | Hospital/Clinical |
| Indices measured | FEV1, FVC, FEV1/FVC, PEF, FEF25-75% +others | FEV1, FVC, FEV1/FVC, PEF, FEF25-75% +others | FEV1, FVC, FEV1/FVC, PEF, FEF25-75% +others |
| Real-time display of each blow | Yes | Yes | Yes |
| Feedback about test quality | Yes | Yes | Yes |
| Flow-volume displayed & printed | Yes | Yes | Yes |
| Volume-time printed | Yes | Yes | Yes |
| Quantifies post bronchodilator change | Yes | Yes | Yes |
| Prints predicted flow-volume curve | Yes | Yes | Yes |
| Includes interpretation software | Yes | Yes | Yes |
| Results download to clinical software | Yes | Yes | Yes |
| Patient result storage capacity | Depending the size of the data storage media | Depending the size of the data storage media | Depending the size of the data storage media |
| Portable/not portable | Portable with laptop PC | Portable with laptop PC | Portable with mobile PC |
| Power source and connection to PC | PC Serial connection | PC USB or Serial connection | PC USB or Micro USB connection |
| ATS compatible | Yes | Yes | Yes |
| Flow Transducer | Disposable | Disposable | Disposable |

| | | | |
|--|---|---|---|
| Flow Transducer Material | HDPE ExxonMobil HDPE HMA 016 | HDPE ExxonMobil HDPE HMA 016 | HDPE ExxonMobil HDPE HMA 016 |
| Pressure Tube Material | TPU (Estane® 58277) and White nylon resin (Zytel 101F) | TPU (Estane® 58277) and White nylon resin (Zytel 101F) | TPU (Estane® 58277) and White nylon resin (Zytel 101F) |
| Size (H x W x L) mm inch | Serial model 16 x 34 x 53 0.63 x 1.34 x 2.09 | Serial model 16 x 34 x 53 0.63 x 1.34 x 2.09 USB model 17 x 36 x 79 0.67 x 1.42 x 3.11 | Nano 14 x 26 x 56 0.55 x 1.02 x 2.20 Primo 13 x 30 x 107 0.51 x 1.18 x 4.21 Pro 13 x 30 x 107 0.51 x 1.18 x 4.21 |
| Weight Grams Ounces | Serial 22 g 0.77 oz | Serial model 22 g 0.77 oz USB 20 g 0.70 oz | Nano 11g 0.39 oz Primo 305g 10.76 oz Pro 305g 10.76 oz |

The new devices have the same intended use and characteristics as the predicate devices.

The new devices have the same intended use, fundamental scientific technology and operating principle as the predicate. Differences between the subject device and the predicates include: the mechanical design of the flow transducers and calculation algorithms for flow.

Nonclinical tests

Following tests were made to the devices:

- AAMI / ANSI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).
- IEC 60601-1-2 Edition 3:2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

- American Thoracic Society and European Respiratory Society (Eur Respir J, 2005, Vol 26, pp. 948-968. No. 5 in SERIES “ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING”)
- ISO 26782:2009, Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans.

Conclusion for Nonclinical tests

Medikro spirometers M913 Medikro® Nano, M914 Medikro® Primo and M915 Medikro® Pro are all tested according AAMI / ANSI ES 60601-1:2005 standard. Testing was performed at CSA group CB testing laboratory. Based on test results Medikro spirometers M913 Medikro® Nano, M914 Medikro® Primo and M915 Medikro® Pro were found to comply with AAMI / ANSI ES 60601-1:2005 standard.

IEC 60601-1-2 EMC testing was made to M915 Medikro® Pro, M913 Medikro® Nano and M911 Medikro® Ambi. EMC testing was made according to IEC 60601-1-2 requirements and includes both emissions and immunity testing. Testing was performed at Savonia Polytechnic EMC laboratory by the laboratory test engineer. Full test reports were made for M915 Medikro® Pro, M913 Medikro® Nano and M911 Medikro® Ambi. Difference between M915 Medikro® Pro and M914 Medikro® Primo is the external casing and that Primo does not measure ambient conditions (same circuit board, but these components are left out).

American Thoracic Society (ATS) 24 standard waveforms test was made for all spirometer units (M915 Medikro® Pro, M914 Medikro® Primo and M913 Medikro® Nano) and all units meet the recommendations for:

- Measuring FVC
- Measuring FEV1
- Measuring FEF25-75%
- Measuring PEF
- Measuring MVV
- Resistance to flow

Testing was done for the Medikro Oy measurement devices against recommendations published by the American Thoracic Society. The essential performance criteria's for spirometers is well defined by the ATS. Spirometers meeting ATS criteria for essential performance are substantially equal. The predicate devices are also designed to meet these ATS criteria.

ISO 26782 test was made for all spirometer units (M915 Medikro® Pro, M914 Medikro® Primo and M913 Medikro® Nano) and all units meet the ISO 26782 requirements for:

- Measuring FVC accuracy and repeatability
- Measuring FEV1 accuracy and repeatability
- Measuring FEV6 accuracy and repeatability
- Linearity
- Impedance

Testing was done for the Medikro Oy measuring devices Medikro Spirometer models Nano, Primo and Pro against recommendations published in the ISO 26782 standard.

Based on these results Medikro spirometers M913 Medikro® Nano, M914 Medikro® Primo and M915 Medikro® Pro are substantially equivalent to the predicate devices. Any differences between the subject and predicate devices do not raise any new questions of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

May 21, 2014

Medikro Oy
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Managing Director
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Re: K133428
Trade/Device Name: M913 Medikro® Nano, M914 Medikro® Primo and M915
Medikro® Pro
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: March 21, 2014
Received: March 24, 2014

Dear Mr. Eloranta,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejasbri Parobit-Sheth, M.D.
Tejasbri Parobit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use
M913 Medikro® Nano, M914 Medikro® Primo and M915 Medikro® Pro

510(k) Number: 133428

Device Names: M913 Medikro® Nano, M914 Medikro® Primo and M915 Medikro® Pro

Indications For Use:

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- adult and pediatric patients 12 years and older,
- hospital and clinic use only.

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anya C. Harry -S
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